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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
NOAKES, SUZANNE MARIE	
ART UNIT	**PAPER NUMBER**
1656	

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06/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/634,027	EVDOKIMOV ET AL.	
	Examiner	Art Unit	
	SUZANNE M. NOAKES	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-32* is/are pending in the application.

4a) Of the above claim(s) *10-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08 May 2008 has been entered.

Status of the Claims

2. Claims 10-32 are pending and claims 10-24 stand withdrawn as they are drawn to non-elected subject matter. Claims 25-32 are subject to examination on the merits.

Withdrawal of Rejections/Objections

3. Any rejection or objection recited previously and not reiterated below is hereby withdrawn.

4. The rejection of claims 25 and 26 under 35 U.S.C. 112 2nd paragraph is hereby withdrawn in view of Applicants amendments to the claims.

5. The rejection of claims 25-32 has been *modified* and thus constitutes a new grounds of rejection.

New Rejections

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The following is from MPEP § 2106.01 and is notably relevant to the instant rejection with regard to whether an invention drawn to non-functional or functional descriptive material is novel or non-obvious

When nonfunctional descriptive material is recorded on some computer-readable medium, in a computer or on an electromagnetic carrier signal, it is not statutory and should be rejected under 35 U.S.C. 101. In addition, USPTO personnel should inquire whether there should be a rejection under 35 U.S.C. 102 or 103. USPTO personnel should determine whether the claimed nonfunctional descriptive material be given patentable weight. USPTO personnel must consider all claim limitations when determining patentability of an invention over the prior art. *In re Gulack*, 703 F.2d 1381, 1385, 217 USPQ 401, 403-04 (Fed. Cir. 1983). USPTO personnel may not disregard claim limitations comprised of printed matter. See *Gulack*, 703 F.2d at 1384, 217 USPQ at 403; see also *Diehr*, 450 U.S. at 191, 209 USPQ at 10. However, USPTO personnel need not give patentable weight to printed matter absent a new and unobvious functional relationship between the printed matter and the substrate. See ** *Lowry*, 32 F.3d **>at< 1583-84, 32 USPQ2d **>at< 1035 **; *In re Ngai*, 367 F.3d 1336, 70 USPQ2d 1862 (Fed. Cir. 2004).

7. Claims 25-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen *et al*. [J. Med. Chem. 1990, 33 (3), 883-889] in view of Fachinger *et al.* (IDS reference 4: Oncogene 1999, Vol. 18, pages 1189-1198) and further in view of *In re*

Gulack 217 USPQ 401 (Fed. Cir. 1983) and *In re Ngai* 70 USPQ2d 1862 (Fed. Cir. 2004).

Cohen *et al*. teach the commercial availability of computers and various packages software used for imaging and identifying potential drugs using atomic coordinates of biological molecules. See in particular section VIII at page 893. This reference has an equivalent teaching to the admitted known prior art in the specification at 10, line11 through page 11, line 26.

Fachinger *et al*. teach a protein named VE-PTP and its functional interaction of a murine protein-tyrosine phosphatase with the angiopoietin Tie-2, see the abstract. Also, they teach that HPTPbeta is the human analog of VE-PTP and suggested that the human have the same function of VE-PTP in regulating Tie-2, see the paragraph that bridge the two columns at page 5952. Also suggested that HPTP beta has a possible role as adhesion receptor, see the previously cited paragraph.

Fachinger *et al.* provide one of ordinary skill in the art with motivation to identify potential modulator for HPTPbeta activity as they teach the biological role of HPTPbetal in regulating Tie-2, which is involved in vascolarization and remodeling of blood vessels. Thus, it would have been obvious to one of ordinary skill in the art to use a commercially available computer equipped with a software package such as GRAM, DUCK, QUANTA and AUTODUCK taught by Cohen *et al.* to fit a model structure of a potential inhibitor to the three-dimensional structure of HPTPbeta to identify possible modulator for HPTPbeta activity. The only difference between the cited prior above and the claimed invention are the atomic coordinates in Figures 7-102 and 202-252. Data, which are fed

into known algorithm such as QUANTA whose purpose is to compare or modify those data using series of processing steps, do not impose a change in the processing steps and are thus nonfunctional descriptive material. A method used for its known purpose to compare data sets does not become non-obvious merely because a new data becomes available for analysis. Nonfunctional descriptive material cannot render non-obvious an invention that has otherwise been obvious. See *In re Gulak*, 703 F2d 1381, 1385 (Fed. Cir. 1983). Atomic coordinates can not render a known method for identifying inhibitors of enzymes novel or non-obvious. It would have been further obvious to the ordinary skilled artisan to synthesize the potential inhibitor and contacting it with HPTPbeta (claim 25-32).

Response to Arguments

8. Applicant's arguments filed 08 May 2008 have been fully considered but they are not persuasive.

Applicants assess what Cohen et al. and Fachinger et al. do teach, and also what they do not. Namely, it is noted that neither of these references do not teach the use of HPTPbeta in a method of *in silico* and rationale drug design. It is specifically stated: "The Office Action has failed to establish a case of obviousness by asserting a combination of the teachings of Cohen and Fachinger. Cohen does nothing more than establish the fact that molecular modeling exists per se. Therefore, Cohen establishes nothing more than what the artisan already knows; computers are used for drug design. Fachinger does not suggest developing a method for identifying a compound that

modulates the activity of HPTPbeta specifically for finding a potential treatment of an angiogenesis mediated disorder. Instead, Fachinger concludes "[f]uture studies toward the identification of potential ligands of VE-PTP will help to clarify its biological activity." Thus Fachinger does not disclose that modulation of VE-TPT, and hence the human homologue, HPTPbeta, activity would lead to a basis for treating an angiogenesis mediated disorder." (See Remarks, p. 8, 2nd full paragraph). Applicants also argue that steps (b) and (c) of claim 25 requires that the user be involved in the positioning of the candidate biding sites for the candidate compounds. It is asserted that there is more than one area that can be a substrate binding site and thus requires user input rather than just the output from a computer program. (see Remarks, p. 7, last full paragraph)

However, it is noted that step (c), which is the analyzing step noted by Applicants, takes place *in vivo* or *in vitro* and thus this analyzing step and user input does not take place *in silico* where the non-functional descriptive material, e.g. the data coordinates of HPTPbeta catalytic domain is utilized. Step (b) only requires "computationally positioning a drug candidate compound at one or more areas...". It is noted that the computer programs as described by Cohen et al. all do this, it is not a single site in which candidate compounds are positioned but many different sites wherein the best fit is subsequently assigned numerical value indicative of how well the compound does or does not bind to various proposed binding sites.

Furthermore, the Examiner disagrees that the claims are non-obvious and that Figures 202-252 and Figures 7-102 are functional descriptive material. The examiner understands that said Figures are not taught in Cohen et al. or Fachinger et al.;

however, it is asserted that the structure coordinates of these Figures are considered non-functional descriptive material and thus are not necessary to render obvious the claimed invention in view of *In re Gulack* and *In re Ngai*.

It is noted that if the difference between the prior art and the claimed invention is limited to *descriptive* material stored on or employed by a machine, it must be determined whether the descriptive material is functional descriptive material or nonfunctional descriptive material. If it is determined that the descriptive material is functional descriptive material and this is a limitation in the claim, then said functional descriptive material must be considered and addressed in assessing patentability under 35 U.S.C. 103. Thus, a rejection of the claim as a whole under 35 U.S.C. 103 is inappropriate unless the functional descriptive material would have been suggested by the prior art. *In re Dembiczak*, 175 F.3d 994, 1000, 50 USPQ2d 1614, 1618 (Fed. Cir. 1999). However, it is noted that *nonfunctional descriptive* material cannot render nonobvious an invention that would have otherwise been obvious. Cf. *In re Gulack*, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983) (when descriptive material is not functionally related to the substrate, the descriptive material will not distinguish the invention from the prior art in terms of patentability). This is especially true in the area of molecular drug design wherein, for example, Dean teaches (see Introduction, BioEssays, 1994, 16(9):683-687):

> "Drug design methods have made significant new advances over the last ten years, mainly in the areas of molecular modeling. In more recent times important developments in theory have led to a different type of modeling becoming possible, the so-called *de novo* or automated design algorithms. In this new method, the programs perform much of the chemist's thinking, in finding appropriately sized chemical groups to fit into a target site".

The examiner would further argue that it is not just in the *de novo* design that the programs perform much of the thinking but also when utilizing pre-existing libraries when screening using these same programs.

Accordingly, in the instant case, it would be obvious to input any three-dimensional structural data into a computer software program as taught by Cohen et al. in order to carry out the software's intended use and function of identifying potential ligands *in silico* by using any readily available data. Said three-dimensional data coordinates do not impart any functionality to the computer itself nor does it impart any functionality itself to the already preexisting computer software programs. It is analogous to stating inputting a set of data into an Excel Spreadsheet imparts functionality to the computer (the computer will run without both the Excel program or the data) that said Excel spreadsheet was loaded onto and/or that said data imparts functionality to the Excel spreadsheet itself. Rather the Excel spreadsheet will still operate in the manner it was designed by inputting any appropriate data set and the functionality of said Excel spreadsheet is not dependent upon any particular set of data. Thus, no one particular data set imparts functionality to the Excel spreadsheet. Likewise, no one particular three-dimensional coordinate data set imparts functionality to the programs taught by Coehn et al. Using these programs in the manner for which they are designed would be obvious. Applicants are also referred to MPEP 2106.01.

In view of the fact that the instant Figures 202-252 and 7-102 are considered non-functional descriptive material, these are not required to be taught in the prior art

according to Gulack and Ngai. Thus, the claims stand rejected as being obvious over Cohen et al. in view of Fachinger.

Conclusion

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUZANNE M. NOAKES whose telephone number is (571)272-2924. The examiner can normally be reached on 7.00 AM-3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Suzanne M. Noakes/
Patent Examiner, Art Unit 1656
10 June 2008